

I, claims 1-3, 8-11 and 13-14. Applicant affirms this election but continues to traverse the restriction requirement for the following reason: Examining the compound claims and the process claims for making the claimed compound in one application would not impose a substantial additional search burden on the Examiner. For economy of time and cost, Applicant requests that the Examiner examine these claims in the same application.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH

Claims 1-3 and 13-14 were rejected under 35 USC 112, second paragraph for being indefinite and for being duplicative. The Examiner states that the Applicant describes a crystalline salt in the specification, and that the hydrochloride has the particular X-ray crystallography fingerprint of claim 3. Thus, according to the Examiner, claims 2, 13 and 14 are redundant.

According to MPEP 706.03(k), Applicant has the "right to restate (i.e., by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough." In independent claim 1, Applicant claims the cephalosporin hydrochloride and hydrobromide salts per se. In narrower, dependent claim 2, Applicant claims only the cephalosporin hydrochloride salt per se. In dependent claim 13, Applicant claims the hydrochloride and hydrobromide salts of claim 1 in crystalline form. And in dependent claim 14, Applicant claims the hydrochloride salt of claim 2 in crystalline form. Therefore, these claims, which vary in scope, are not redundant.

Also, these claims are not indefinite because each of these claims is clear as to what Applicant is claiming. In claims 1 and 2, Applicant is claiming the cephalosporin hydrochloride and hydrobromide salts per se. And in claims 13 and 14, Applicant is claiming the crystalline form of these salts.

Therefore, for the above reasons, the rejection under 35 USC 112, second paragraph, should be withdrawn.

REJECTION UNDER 35 USC 103

Claims 1-3, 8-11 and 13-14 are rejected under 35 USC 103 as being unpatentable over Labeeuw et al. 4,464,367. According to the Examiner, Labeeuw teaches the free acid and salts of the instant compound useful for the same utility, and that absent additional evidence, the instant crystalline compounds are patentably indistinct over the art.

The Labeeuw et al 4,464,367 patent discloses the same cephalosporin

antibiotic compound used by Applicants here to make the claimed hydrohalide salts. That cephalosporin is now known by its accepted generic name, ceftiofur (in France). All of the salt groups disclosed in the Labeeuw patent refer to salts of the carboxyl group in the 4-position of the usual cephalosporin nucleus ring system. See column 1, lines 30-43, and column 3, lines 40 to 54. The present invention relates to hydrohalide salts of the free amino group in the 7-position side chain thereof. No where does Labeeuw teach or suggest the salts of the present invention. Furthermore, the Examiner has presented no secondary references that would teach or suggest the salts of the present invention. Therefore, claims 1-3, 8-11 and 13-14 are patentably distinguishable over the Labeeuw patent.

However, in order to expedite prosecution of this application, provided herewith is a Declaration of the co-inventor, Mahendra I. Amin, which verifies the pharmaceutical handling advantages of the hydrochloride salt in terms of its longer shelf life and of its adaptability to various pharmaceutical formulations.

Also enclosed herewith is a Declaration by co-inventor Jay A. Campbell, verifying more pharmaceutical handling advantages of the hydrochloride salt, especially its improved purity and stability.

On the basis of the above remarks, reconsideration of this application and its early allowance are requested.

Respectfully submitted,

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Attachments:

U.S. Patent 4,624,948  
EP 0 222 577  
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Declaration: Jay A. Campbell